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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,227	07/02/2007	**Paul Kemp**	DFBP:075US/11001662	5775

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EXAMINER	
EPPS -SMITH, JANET L	

ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
02/11/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/589,227	KEMP ET AL.	
	Examiner	Art Unit	
	Janet L. Epps-Smith	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,8-10,13-15,17-19,23-28,39-42,44,46 and 48-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,8-10,13-15,17-19,23-28,39-42,44,46 and 48-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

1. 1, 4, 8-10, 13-15, 17-19, 23-28, 39-42, 44, 46, and 48-51 are presently pending for examination.

2. Claims 52-62 are cancelled.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 4, 8-10, 13-15, 17-19, 23-28, 39-42, 44, 46, 48-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (New Matter).

5. Claim 1 has been amended in the following manner:

> 1. (currently amended) A wound healing composition comprising living human dermal fibroblast cells suspended within a single layered sterile, non-pyrogenic, solid or semi-solid, support matrix, said support matrix comprising a protein concentration of 3 to 12 $mg.ml^{-1}$ and a cell density of said human dermal fibroblasts of 450 to 2500 cells per mm^2, ~~in which the cells have a wound healing phenotype, and in which the composition is single-layered and~~ said composition having ~~has been incubated for up to about 8 days to allow development of the wound healing phenotype~~ 16 to 24 h at about 37°C.

Applicants have amended claim 1 to recite "human dermal fibroblast cells" suspended within a "single layered sterile, non-pyrogenic, solid or semi-solid, support matrix...."

The only support in the specification as filed for "human dermal fibroblasts within a sterile, non-pyrogenic support matrix.." is in reference to a support matrix formed by a thrombin-mediated polymerisation of fibrinogen, and in which the composition has been incubated for 16 to 24 hours at about 37°C," see ¶ [0051] and original claim 21. Applicants have taken limitations from original claim 21 and combined them with limitations from original claims 13-14, and 20. However, neither the specification as filed, nor the original claims provide support for this combination.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1, 4, 8-10, 13-15, 17-19, 23-28, 39-42, 44, 46, 48-51 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Leek et al. (WO 2002/072113A1) in view of Herlyn et al. (US20040031067A1), Drohan et al. (US7196054) and Harichian et al. (US20020018757) for the reasons of record set forth in the Office Action of 5-26-2010.

8. Applicant's arguments filed 11/24/2010 have been fully considered but they are not persuasive. Applicants traversed the instant rejection on the grounds that Leek et al. fails to disclose or suggest several of the elements in the above claim such as the single layered, sterile, non-pyrogenic, protein concentration, cell density, and incubation period and temperature limitations..

9. Contrary to Applicant's assertions, the instant claims are drawn to a wound healing composition *comprising* living human dermal fibroblast cells suspended within a single layered sterile, non-pyrogenic, solid or semi-solid support..." Thus, although Applicants argue that Leek does not disclose a composition comprising a single-layer of human dermal fibroblast. The compositions of Leek et al. are clearly disclosed as comprising cells having a wound healing phenotype, wherein the cells are fibroblast, and wherein cells are in a matrix-forming cell delivery vehicle. The composition is substantially free of other cell types, and comprises at least 90% fibroblast. Additionally, the matrix or scaffold forms around the cells in the composition. Page 5, lines 3-6 recites the following:

> The fibroblasts may be mammalian, preferably human. The invention provides that the cells could be allogeneic cells, i.e. the cells administered to a patient would be from a donor.

10. According to the specification as filed at ¶ [0027], "The term "single-layered" indicates that the composition has only one layer containing cells within a support matrix, i.e. it is not a multi-layered "skin equivalent" with multiple layers of (different) cells. However, the invention also encompasses compositions having additional non-cellular layers as well as compositions having stacked layers comprising substantially uniform single layers." The teachings of Leek et al. disclose a support matrix comprising fibroblast, preferably human, wherein the support matrix is substantially free of other cell types. Absent evidence to the contrary, this embodiment of Leek et al. read

on the claimed invention to the extent that it is drawn to a composition *comprising* living human fibroblast suspended within a single layered solid support matrix.

11. Although Applicants assert that Herlyn et al. teach a multi-layered composition, Herlyn et al. (US20040031067A1) teaches compositions for wound healing, wherein said composition *comprises* a matrix containing a monolayer of human dermal fibroblast, see ¶ [0039]. As stated above the instant claims are drawn to a wound healing composition comprising a single layered sterile, non-pyrogenic, solid or semi-solid support matrix.

12. Regarding Drohan et al. (US 7196054B1), Applicants argued that the teachings of this reference rely on a non-living tissue sealant to bring about its objective. Contrary to Applicant's assertions, Drohan et al. also encompasses the following embodiment which does not rely upon non-living tissue sealant to bring about its objective: "[T]he Cartilage Inducing TS (CI-TS) mixture can also be used to precoat a conventional implant, with the result being a conventional implant with a coating of living cartilage." (See cols. 67-68, example 24)

13. In response to Harichian et al. (US 20020018757A1), Applicants argue that this reference does not suggest using living cells, much less human dermal fibroblast, for treating wounds. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Furthermore, Contrary to Applicant's assertions, the

compositions of Harichian et al., which comprise the protease inhibitor aprotinin, are disclosed to function in the stimulation of collagen synthesis. According to the specification as filed, the fibrin matrix used in the compositions of the instant invention is designed to increase the synthesis of collagen by entrapped fibroblast. The ordinary skilled artisan seeking to increase the activity of a fibrin matrix would have been motivated to combine aprotinin with the matrix since the prior art teaches that this compound and the fibrin matrix both function to stimulate collagen synthesis, see MPEP § 2144.06 which teaches that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850,205 USPQ 1069, 1072 (CCPA 1980)

14. Furthermore, as stated in the prior Office Action, it would have been obvious to the ordinary skilled artisan to modify the teachings of Leek et al. with the teachings of Herlyn et al., Drohan et al., and Harichian et al. in the design of the instant invention. Absent evidence to the contrary, one of ordinary skill in the art would have been motivated to make this modification since the compositions disclosed in each reference are disclosed as useful in the treatment of various disorders associated with the skin.

15. Regarding the rationale for combining prior art elements according to known methods to yield predictable results, all of the claimed elements were known in the prior art and one skilled in the art could have combined the element as claimed by known

methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Claim Rejections - 35 USC § 112

16. The rejection of claim 25 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Smith whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/
Primary Examiner, Art Unit 1633